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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,033	01/04/2006	Warren Ward	WAW0101PUSA	1595

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,033	WARD, WARREN	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-6, 12-23, and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11,24-28,30-33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed April 07, 2009. Claims 1-36 are currently pending. Claims 7-11, 24-28, and 30-33, and 36 are under consideration in the instant office action. Claims 1-6, 12-23, and 34 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 29 and 35 are cancelled. Applicant's declaration submitted under 37.C.F.R. § 1.132 is also acknowledged. Applicant's amendment has necessitated a new ground of rejection such as under 35 U.S.C. 112.

Priority

The examiner acknowledges the earliest effective filing date afforded for the instantly claimed invention, has been determined to be 07/19/2004, the filing date of the international application PCT/GB04/03104.

Withdrawn rejections:

Applicant's amendments and arguments filed on 04/07/09 are acknowledged and have been fully considered. The rejections applied in the previous office action under the first paragraph of 35 U.S.C. 112 for lack of evidence for the encapsulating layer being gas permeable is hereby withdrawn as a result of applicants claim amendments and persuasive arguments.

Claim Rejections - 35 USC §101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility. The instant application fails to provide adequate evidence to support the utility of the invention. Specifically, there is insufficient evidence to show that a compound which is not released on or into the body can have any medically beneficial effect. Additionally, the agents used to form the liquid impermeable but gas permeable layer (e.g. wax) are also used in the art to form controlled release formulations of drugs.

Response to Arguments

Applicant's arguments filed on April 07, 2009 have been fully considered but they are not persuasive. Applicant argues that the invention is a device and not a pharmaceutical. The examiner respectfully disagrees with the argument because the claim language does not recite a device but a preparation. There is no mention of a medical device in the claim recitation. Moreover, the forms of the claimed preparation listed in instant claims 25-28 are forms commonly known and used in the pharmaceutical arts and claim 24 recites "for use as a medicament", which is sufficient evidence that the claim language recites a pharmaceutical formulation.

Additionally, applicant argues the medically efficacious substances such as sodium chloride which are encapsulated are sensed by the body without being released into, absorbed by, or metabolized by the body via cell signaling. This is not persuasive because the examiner can find no evidence to that effect presented by the applicant. As a matter of fact, Rastogi in *Cell and Molecular Biology*, indicates two systems for cellular communication: chemical messengers and nervous system (page 158, section 6.4).

Chemical messengers bind to receptors to initiate cell signaling while neurons communicate using electrical potentials. The instantly claimed invention does not fit under either category. Medically efficacious substances released into the body can bind to and either activate or inhibit a receptor; the instantly claimed invention, wherein the substance is not released, cannot. Ions such as sodium can be used to create electrical potential differences across a cell membrane. Changes in the ion concentration and, therefore, the electrical potential can be used for communication. The instantly claimed invention wherein, for example, the sodium chloride is not released into the body, would not be expected to generate a difference in the electrical potential across a cell membrane. Rastogi also indicates that environmental factors such as pH, temperature, etc. may act as stimuli (page 159, section 6.4). The instantly claimed invention is not an environmental factor. Neither is there any evidence to suggest that the instantly claimed invention initiates or causes a change in the environment. Rather, the evidence is that the medically efficacious substance is not released and, therefore, does not effect the surrounding environment.

Finally, applicant argues that the commercial success of the "Equiwinner" patches is evidence of utility. The examiner respectfully disagrees with this assertion because the commercial success of the so called "Equiwinner" patches does not constitute a scientifically grounded study regarding the utility of the instantly claimed invention. Commercial success may be grounded in anecdotal evidence, good advertising, etc, and not necessarily based on the actual effectiveness and utility of the instantly claimed invention. Moreover, the argument that "products according to one or more embodiments of the applicant's invention…" is not sufficiently specific to ascertain to

which claim limitations the proposed evidence of the "Equiwinner" patches is supposed to apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 7-11, 24-28, 30-33, and 35-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. The specification does not reasonably provide enablement for how to use the claimed preparation or composition for the treatment of diseases. Applicant does not provide adequate evidence to substantiate the fact that a drug coated such that the drug that is prevented from release is surly effective. Applicant provides no evidence to substantiate the assertion that a drug which is not released is effective at treating any diseases.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope of breadth

of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims

The breadth of the claim is a medically efficacious substance which is coated with a liquid impermeable but gas permeable layer such that the medically efficacious substance is prevented from release.

Nature of the invention

The nature of the invention is directed to the treatment of blocked or malfunctioning exocrine glands using a medically efficacious substance coated in a liquid impermeable but gas permeable layer.

Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular area possess M.D. and/or Ph.D. in a scientific discipline such as medicinal chemistry, biochemistry, pharmacology, biology, organic synthetic chemistry or the like.

State of, or the amount of knowledge in, the prior art

The art teaches the coating of drugs or other medically efficacious substances for controlling the release of the drug. Coated drugs are well known and include, e.g., aspirin (US patent 4508702, abstract); applicant teaches the use of coated aspirin in example 3 in the specification. The prior art does not recognize the treatment of diseases with drugs which are never released.

Level or degree of predictability, or a lack thereof, in the art

Currently, there are well established methods of coating drugs. Specifically, the use of polymers, ceramics and waxes including natural wax and beeswax for coating drugs are known in the art (US Patent No 5827538, see the whole document). However, even drugs coated with polymers, ceramics and waxes including natural wax and beeswax are designed for the controlled release of the encapsulated drug. No prior art, however, teaches a coated drug which is not released upon administration. Moreover, there is no prior art that predicts that such a drug which is not released would be efficacious.

Presence or absence of working examples

The specification fails to provide scientific data and working examples with respect to the effectiveness of the coated drugs which are not released. The information provided in the examples does not meet the currently accepted scientific standards for determining the efficacy of new pharmaceutical compositions. The currently accepted practice uses double blind controls in which one group receives the new drug and a control group receives a placebo; neither group knows whether it receives a placebo or the new drug being tested. The examples given in the specification do not have control groups. Moreover, patients know when they are receiving the ActivSignal form versus

the standard form of the drug. Additionally, the agitation of coated medically efficacious substances in acidic or alkaline water is inadequate to justify the assertion that the coating is impermeable to liquids generally. It is also inadequate to ensure that the medically efficacious substance is not released upon administration to the subject since acidic and basic water do not adequately simulate all biological fluids that might be encountered by the coated medically efficacious substance upon administration to a subject. Moreover, applicant fails to specify the acid or base used and the pH of the resulting solution.

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the composition of the instant application is not released and moreover to determine whether a drug which is not released is effective.

Response to Arguments

Applicant's arguments filed on April 07, 2009 have been fully considered but they are not persuasive. Applicant argues the prior art neither teaches nor suggests the effectiveness of a medically efficacious substance which is not released. The applicants then argued the same arguments made under the rejection of the instantly claimed invention under 35 USC 101. The examiner, therefore, directs applicant to the responses set forth above for the rejection under 35 USC 101 regarding applicant's arguments to the instantly claimed invention. Furthermore, applicants argued as evidence for the indirect action of a medically efficacious substance by citing the 2003 Nobel lecture of MacKinnon. However, the examiner respectfully disagrees with applicant's assertion

(because the pattern of water molecules around the instantly claimed preparation would not be expected to resemble the pattern of water molecules around an ion such as sodium or potassium, which are described in the lecture. In particular, the size of the ion is important in the recognition process of the corresponding ion channel and the particle size of the encapsulated medically efficacious substance is bigger than a single ion. The work of MacKinnon relates to the recognition of aqueous ions by ion channels and does not relate to encapsulated ions which are not released. Moreover, other encapsulated medically efficacious substances of the instantly claimed invention (e.g. aspirin) are even less related to MacKinnon's work on ion channels.

New Claim Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, in the claim amendment the recitation "substantially preventing release of the medically efficacious substance" lacks support in

the original disclosure. The specification provides support, for example, the coating surrounding the sodium chloride (e.g. sodium chloride crystals or granules) may be any liquid impermeable but gas permeable barrier "**which prevents the sodium chloride from passing into (e.g. when ingested) or onto the body"(page, lines 1-4)** . The specification also provides support during administration of the agent, the substance (the sodium chloride or other agents as detailed below, coated with/encapsulated by the agent) to a patient may result in no metabolic change to, chemical change to, or diminution of, the sodium chloride (or other substance as detailed below) (page 6, lines 23-26). From the above disclosure one of ordinary skill in the art can infer that the agent is completely prevented from release. Therefore, the incorporation of the term "substantially" is not supported by the original disclosure.

Claims 7-11, 24-28, 30-33, and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 24 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what level "substantially" constitutes. It is not clear at what amount the agent is released.

Additionally, the examiner was unable to ascertain the meets and bounds of the claimed invention because as written the claims are vague and indefinite. Even if applicant amended the claims the general scope of the invention is still unclear. The

claim language recite a preparation for use as a medicament, wherein the agent is substantially prevented from release and dependant claims also recite known pharmaceutical forms such as a tablet, a capsule etc. It is not clear whether the instantly claimed invention is pharmaceutical formulation since it is not substantially released. The claims as written, therefore, are unsearchable. Therefore, the examiner still did not apply any art in the rejection of the claimed invention.

Conclusion

Claims 7-11, 24-28, 30-33, and 36 are rejected. Claims 1-6, 12-23, and 34 remain withdrawn. Claims 29 and 35 are cancelled. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 6/18/09

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616